FORM PTO-1390 (REV 10-95) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER: HUBR 1099-PFF/MCS

U.S. APPLICATION NO. (If known, see 37 CFR 1.5): 08/732408

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/EP95/01357	12 April 1995	22 April 1994

TITLE OF INVENTION: MEDICAL IMPLANTS MADE OF MOULDINGS

Rec'd PCT/PTO 22 OCT 1996

APPLICANT(S) FOR DO/EO/US: Johannes Reinmüller

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. [X] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [X] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] has been transmitted by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [X] A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. [X] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendemnts has NOT expired.
   d. [X] have not been made and will not be made.
8. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [X] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (unexecuted)
10. [X] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern document(s) or information included:

11. [ ] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [X] A FIRST preliminary amendment.
    [ ] A SECOND or SUBSEQUENT preliminary amendment.
14. [ ] A substitute specification.
15. [ ] A change of power of attorney and/or address letter.
16. [X] Other items or information:
    Copy of International Search Report (in German)
    Cover sheet of published International Application PCT/EP95/01357

"Express Mail" mailing label Number EH184923450US
Date of Deposit October 22, 1996
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Washington, D.C. 20231.

FELFE & LYNCH

Samuel Rodon
(Printed name)

Samuel Rodon
(Signature)

(January 1996)

U.S. APPLICATION NO (if known, see 37 CFR 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
	PCT/EP95/01357	HUBR 1099-PFF/MCS

17. ☒ The following fees are submitted:

	CALCULATIONS	PTO USE ONLY
BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)):		
Search Report has been prepared by the EPO or JPO **$880.00**		
International preliminary examination fee paid to USPTO (37 CFR 1.482) **$680.00**		
No international preliminary examination fee paid to USPTO (37 CFR 1.482) but international search fee paid to USPTO (37 CFR 1.445(a)(2)) **$750.00**		
Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$1010.00**		
International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(2)-(4) **$94.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$ 910.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$	

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	16 - 20 =	0	X **$22.00**	$	
Independent claims	1 - 3 =	0	X **$78.00**	$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ **$250.00**	$	
TOTAL OF ABOVE CALCULATIONS =				$ 910.00	
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also by filed (Note 37 CFR 1.9, 1.27, 1.28).				$	
SUBTOTAL =				$ 910.00	
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492(f)).			+	$	
TOTAL NATIONAL FEE =				$ 910.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property			+	$	
TOTAL FEES ENCLOSED =				$ 910.00	
				Amount to be: refunded	$
				charged	$

a. ☒ A check in the amount of $ 910.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. _____ in the amount of $_____ to cover the above fees. A duplicate copy of this sheet is enclosed.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 06-0530 . A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

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SIGNATURE

Mary Anne Schofield
NAME

36,669
REGISTRATION NUMBER

Medical implants made of ~~structural elements~~ MOULDINGS

~~BACKGROUND AND SUMMARY OF THE INVENTION~~

Field of the Invention

~~DESCRIPTION~~

This invention concerns plastic implants for medical purposes and in particular implants composed of thin foldable structural elements.

In human and veterinary medicine congenital or acquired organ or soft-tissue defects are filled using plastic implants (PI) which are operatively introduced into the organism. In contrast to orthopaedic implants or to artificial organs which are also implanted in the organism, the object of the aforementioned plastic implants is to provide volume substitution of soft-tissues and in a particular embodiment to effect stretching and distension of tissue especially of skin tissue.

Typical examples of PI include the substitution of missing mammary tissue by silicone pads which are implanted in front of or behind the pectoral muscle or implants to substitute missing testicles. Examples of implants for stretching and distending tissue to construct soft parts in the face, at the extremities or on the torso are conventional expanders such as e.g. the Becker expander as described by Joseph G. McCarthy, Plastic Surgery (1990), W.B. Sounders Comp., Volume 1, chapter 13, p. 486.

In order to achieve a reconstruction of soft tissues which looks as natural as possible materials are preferably used for plastic implants whose mechanical

properties are very close to those of natural tissues. In addition it is required that the implant material used is physiologically compatible, does not have toxic effects and has an extreme chemical and mechanical long-term stability. In general elastically deformable plastics fulfil these requirements especially in the form of gels. The use of dimethylsiloxane polymers (PDMS) have proven to be particularly advantageous due to their excellent chemical stability.

Conventional implants comprise an outer covering made of silicone material into the interior of which a high-polymer gel e.g. a PDMS gel is introduced or aqueous solutions. The gel or aqueous solution can be added before the implantation or in the case of an aqueous solution subsequent to implantation using a valve which is accessible from the body surface. Such implants have for example been disclosed in US Patent No. 4428364, 4574780, 4671255 and 4840615.

However, conventional products which use gels and especially products which use PDMS gels have the disadvantage that when the outer covering is damaged, e.g. in an accident, the surrounding tissue is infiltrated with (PDMS) gel under high pressure. Afterwards such a situation can hardly be brought under control by surgical measures. Moreover, recent investigations have raised doubts about the physiological compatibility of the PDMS implants. It is assumed that lower-molecular components of PDMS gels diffuse through the outer covering and thus reach the surrounding tissue causing long-term irreversible injury to health. Although, this penetration can be reduced by introducing barrier layers, it cannot be avoided completely.

Attempts to replace PDMS gels by other materials due to the aforementioned disadvantages have not yet led to a satisfactory result:

Physiological saline solutions are not suitable since as a filler material they give a plastic implant undesired mechanical and compression elasticity properties. In addition such implants lose their liquid volume within a few years since the outer covering made of PDMS rubber is not a barrier for lower molecular substances.

The use of other substitutes such as e.g. hydrogels, dextrans, hylanes, gelatins or polyvinyl-pyrolidone (PVP) is disadvantageous due to their poor long-term stability or is limited due to their toxicity.

The object of the present invention was therefore to provide a plastic implant which ensures the advantages of PDMS gels i.e. compression elasticity and thus tissue-like properties as well as chemical long-term stability but at the same time does not have the aforementioned disadvantages i.e. diffusion of lower molecular toxic components into the surrounding tissue and infiltration of the surrounding tissue with PDMS gel when the outer covering is damaged.

Summary of the Invention

This object is achieved according to the present invention by an implant for ~~medical purposes~~ reconstructive soft tissue surgery based on a physiologically compatible plastic which is composed of thin foldable structural elements with a surface that can be wetted by a fluid lubricant.

The volume of the implant is in this case usually determined by the thin structural elements whereas the

volume of lubricant is not as important. In order to construct an implant according to the invention thin foils are for example used as the structural elements wherein numerous layers lying on top of one another yield an implant of the desired thickness.

The desired tissue-like elastic properties of the implant of the present invention are essentially achieved by the ability to displace adjacent layers of the thin foldable structural elements, the sliding effect being mediated and facilitated by a suitable lubricant.

The structural elements of the present invention can either be introduced without an outer covering directly into a pre-formed implant pocket in the tissue or, like conventional implants, they can be surrounded by an outer covering in which case the gels of conventional implants are replaced by structural elements of the present invention.

DETAILED DESCRIPTION

All physiologically compatible plastics come into consideration as materials for the structural elements. The term "physiologically compatible plastics" in this application generally means naturally occurring and artificially produced materials or biomaterials that are physiologically compatible. In a particular embodiment the structural elements are composed of silicone rubber, silicone rubber made of polydimethylsiloxane being preferred. In a further embodiment structural elements made of polysaccharides are used in which case structural elements made of cuprophane foil represent a preferred embodiment. However, the invention is not limited to the aforementioned materials and other

Description of the Preferred Embodiments

physiologically compatible plastics and biomaterials which can be processed to form thin structural elements are part of the present invention.

The thin foldable structural elements of the invention can be provided in various embodiments. It is preferable to use a foil (thin sheet) which is folded in a suitable manner or to use several layers of foil which lie on top of one another and are cut to make the shape of the final implant. It has been found that it is advantageous to use foils having a thickness of about 5 to about 500 µm, 10 to 200 µm being preferred and 30 to 70 µm being especially preferred. In a further embodiment of the invention the structural elements are provided in the form of capillary tubes or in a tubular form. It is also possible to use the structural elements in a strand form ("silicone spaghetti"). In this connection it is possible to achieve better results using smaller strand thicknesses with regard to the tissue-like properties of the implants. However, it is preferred for technical reasons to use strand thicknesses between 0.1 and 1 mm.

The present invention is not limited to the aforementioned embodiments and other embodiments such as for example loose open-pored plastic foams are also a subject matter of this invention. In some cases it may be particularly expedient to use a combination of two or several embodiments. Such combinations are also encompassed by the present invention.

The implants of the invention can be monitored post-operatively after introduction into the tissue. PDMS foils are for example more dense than tissue towards X-ray radiation which enables the position of an implant

to be monitored postoperatively by means of an X-ray examination. Implants according to the invention which comprise structural elements made of PDMS are thus accessible to a postoperative examination without further additives. In other cases the addition of suitable materials that can be detected from the outside such as for example X-ray contrast agents in the plastic enable the implants to be monitored later in a simple manner.

The tissue-like properties of the implants of the present invention are mainly based on the sliding ability of adjacent layers of the thin structural elements, the sliding ability being facilitated by a suitable fluid lubricant.

The term "fluid lubricant" according to this application is in general understood as liquid and fluid phases which are physiologically compatible and which enable or/and improve the movement of surfaces of adjacent structural elements. The type of lubricant used only depends on the surface of the structural element used. In the case of a hydrophilic surface of the structural elements a hydrophilic fluid is also used as a lubricant. Sliding mediated by hydrophilic interactions is the preferred embodiment in which case it is especially preferable to use an aqueous liquid as the lubricant. Accordingly the sliding ability can also be achieved by using hydrophobic surfaces/lubricants, fats and oils being in this case preferred as hydrophobic lubricants. Sliding processes mediated hydrophilically/ hydrophobically e.g. by liposomes or micelles of ampholytic substances are also a subject matter of this invention.

In many cases it can be advantageous to adapt the surfaces of the thin structural elements to the properties of the lubricant used by hydrophobization or hydrophilization in order to further improve their sliding ability. Corresponding processes are well-known to a person skilled in the art. The hydrophilization of silicone surfaces is for example described in DE-OS 4216271 by etching with a solution of KOH in methanol. EP-A-0 086 186 describes the hydrophilization of surfaces containing amines with substances that contain 2-amino-2-deoxyglycopyranosil residues. Suitable processes for hydrophobization for example include applying silicone layers or waxes.

The use of structural elements with hydrophilized surfaces represents a particularly advantageous application of the structural elements of the present invention. The hydrophilization binds the lubricant, preferably water, inside the implants and thus effectively prevents loss of volume by diffusion as occurs in conventional implants based on liquids. In this embodiment the implants of the present invention can optionally be implanted without addition of lubricant. In this case the lubricant is provided by the surrounding tissue since tissue fluid can diffuse into the inside of the implants and if present through the outer covering.

In a further preferred embodiment the implants of the present invention contain swellable materials. Suitable swellable materials for producing structural elements according to the invention are in general all physiologically compatible substances which can swell on contact with a suitable liquid. It is particularly advantageous to use polysaccharides, the polysaccharide

cuprophane foil being particularly preferred. In this case water is the swelling as well as lubricating agent.

However, the use of swellable materials is not limited to the structural elements but rather a swellable lubricant can be used instead of or in addition to swellable structural elements. Suitable swellable lubricants are for example anhydrous polysaccharides, glycosaminoglycans, dextrans and such like. Hyaluronic acid is preferred. Further suitable swellable materials are known to a person skilled in the art.

In addition the implants of the present invention contain other additives such as dyes, antioxidants, stabilizing agents, disinfectants, antibiotics, salts and such like as needed or depending on the intended use.

The implants of the present invention are either used as soft tissue substitutes or to expand surrounding tissue. The plastic implants are usually surrounded by an outer elastic covering, the form of the implants being determined by the dimensions of the outer covering. Taut elastic properties can be achieved to a greater or lesser extent by overfilling or underfilling the outer covering with the structural elements according to the invention. The lubricant usually only fills the capillary gaps which occur between the layers of the filling material and thus makes only a slight contribution to the filling volume. As an alternative an implant according to the invention can be underfilled with swellable structural elements and/or lubricant in which case the final volume of the implant is determined in advance by the fill quantity and the given

swellability of the materials but is only achieved after implantation.

A particular type of application of the implants of the present invention is as so-called tissue expanders which are only subsequently brought to their final volume after implantation or incorporation of the expander. In this case a change in volume is regulated by addition or removal of lubricant. Similarly to the known Becker expander it is possible to remove the valve mechanism after the desired expander volume has been achieved by which means the expander containing the filling according to the invention becomes a permanent implant.

The advantages of the present invention are essentially that the thin foldable structural elements which represent the filling material of the implants according to the invention have the same long-term stability as the conventional outer covering material. The release of toxic substances over a long time period is considerably reduced by this. In addition the filling material is not dispersed into the surrounding tissue in an uncontrolled manner as is the case with conventional PDMS gels when the outer covering is damaged but can be removed surgically in a complete and simple manner. Released lubricant is taken up by surrounding tissue or mixes with tissue fluid without detrimental effects for the organism. In a preferred embodiment a great advantage is the simple sterilizability in an autoclave when using structural elements made of hydrophilized PDMS foil and water as the lubricant.

The present invention is illustrated by the following examples.

EXAMPLE 1
Hydrophilization of silicone surfaces

Silicone rubber foils with a thickness of 0.02 mm, 0.2 mm and 0.3 mm and strand-like silicone rubber (silicone spaghetti) are hydrophilized by etching with a solution of 5.7 g KOH in 100 ml methanol as described in DE-OS 4216271.

EXAMPLE 2
Mammary implant

A covering of silicone rubber is produced with an elliptical cross-section and a circular longitudinal section with a wall thickness of 0.2 mm. Hydrophilized silicone rubber foil of thickness 0.02 mm from example 1 is introduced through an opening. The outer covering has a capacity of 200 ml in the relaxed state. The amount of added filling material corresponds to a volume of 190 ml. A volume of 10 ml water is also added to the interior. The filling aperture is tightly closed. The mammary implant produced in this way is degassed in a vacuum chamber and afterwards sterilized in an autoclave.

EXAMPLE 3
Lip implant

A length of hydrophilized silicone rubber foil from example 1 with a thickness of 0.02 mm and 4 cm in length and 6 cm in width is rolled up to form a round body. This round body is pulled into the upper lip with the

aid of an awl through small incisions in the area of the angle of the mouth. The incisions are closed by stitches.

EXAMPLE 4
Gluteal implant

A silicone rubber covering is produced with an oval shape and a wall thickness of 0.3 mm and capacity of 180 ml. Hydrophilized silicone rubber from example 1 is introduced through an opening as round material with a diameter of 1 mm in an amount which corresponds to a volume of 170 ml. 8 ml water are additionally added. The covering is tightly sealed. The implant is degassed and autoclaved.

EXAMPLE 5
Skin expander

A silicone rubber covering is produced in a rectangular form with rounded corners and edges. It is hydrophilized internally and externally as in example 1. Foil material made from cellulose acetate with a thickness of 0.01 mm is added through an opening. A powder made of anhydrous cross-linked hyaluronic acid is interspersed between the individual layers of the foil. The covering is tightly sealed and the implant is autoclaved. After implanting the implant prepared in this way into the organism, for example into subcutaneous tissue, water penetrates into the interior through the silicone rubber covering and leads to a swelling of the filling material. The implant expands spatially and in this process expands the skin. The time-course of the increase in size is regulated by the inflow of water. The final volume of the skin

expander is defined in advance on the basis of the swellability of the filling material by the amount of filler introduced.

Claims

It is claimed

1. Implant for medical purposes based on a physiologically compatible plastic,
w h e r e i n
it is composed of thin foldable structural elements having a surface that is wettable by a fluid lubricant.

2. Implant as claimed in claim 1,
w h e r e i n
it is surrounded by a covering.

3. Implant as claimed in claim 1 or 2,
w h e r e i n
it has the shape of a foil with a thickness of 10 to 200 µm.

4. Implant as claimed in claim 1 or 2,
w h e r e i n
it has a strand form with a thickness of 0.1 to 1 mm per strand.

5. Implant as claimed in claim 1 or 2,
w h e r e i n
it is composed of tubular foils.

6. Implant as claimed in one of the claims 1 to 5,
w h e r e i n
it has a hydrophilized surface.

Sub A4 cont

7. Implant as claimed in claim 6,
w h e r e i n
it contains an aqueous fluid as the lubricant.

8. Implant as claimed in one of the previous claims,
w h e r e i n
the thin foldable structural element is capable of swelling when contacted with a suitable liquid.

9. Implant as claimed in one of the previous claims,
w h e r e i n
the lubricant is swellable.

10. Implant as claimed in claim 9,
w h e r e i n
the lubricant is a polysaccharide or glucosaminoglycan.

11. Implant as claimed in one of the claims 1 to 5,
w h e r e i n
the thin foldable structural element has a hydrophobized surface.

12. Implant as claimed in claim 11,
w h e r e i n
it contains fat or oil as the fluid lubricant.

13. Implant as claimed in one of the previous claims,
w h e r e i n
the plastic is a silicone rubber.

Sub A1

14. Implant as claimed in claim 13,
w h e r e i n
the silicone rubber is composed of polydimethyl-siloxane.

Cont

15. Implant as claimed in one of the claims 1 to 10,
wherein
the plastic is a polysaccharide.

16. Implant as claimed in claim 8, 9 and 15,
w h e r e i n
the polysaccharide is cuprophane foil.

17. Implant as claimed in one of the previous claims,
w h e r e i n
the foldable structural element has a foam structure.

18. Implant as claimed in one of the previous claims,
w h e r e i n
an X-ray contrast medium or a dye is incorporated into the plastic of the structural element.

add B5

add C1

add G1

add J

ABSTRACT

An implant for medical purposes based on a physiologically compatible plastic is composed of thin foldable structural elements of foil having a thickness of 10 to 200 micrometers having a surface that can be wetted by a fluid lubricant and is preferably surrounded by a covering that contains a lubricant such as e.g. an aqueous fluid.

COMBINED DECLARATION FOR PATENT APPLICATION AND POWER OF ATTORNEY
(Includes Reference to PCT International Applications)

ATTORNEY'S DOCKET NUMBER
HUBR 1099 PFF/MAS

08/732,408

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Medical Implants made of Mouldings

the specification of which (check only one item below):

☐ is attached hereto.

☐ was filed as United States application

Serial No. _____

on _____.

and was amended

on _____ (if applicable).

☒ was filed as PCT international application

Number PCT/EP95/01357

on 12/April/1995;

and was amended under PCT Article 19

on ./. (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowlege the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed:

PRIOR FOREIGN/PCT APPLICATION(S) AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. 119:

COUNTRY (if PCT indicate PCT)	APPLICATION NUMBER	DATE OF FILING (day, month, year)	PRIORITY CLAIMED UNDER 35 USC 119
Fed.Rep. of Germany	P 44 14 103.3	22/April/1994	☒ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO
			☐ YES ☐ NO

(January 1991)

Combined Declaration For Patent Application and Power of Attorney (Continued)
(Includes Reference to PCT International Application)

9 DEC 1996

ATTORNEY'S DOCKET NUMBER
HUBR 1099
PFF/MAS

08/1337
408

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) or PCT international application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT international filing date of this application:

PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS DESIGNATING THE U.S. FOR BENEFIT UNDER 35 U.S.C. 120:

U.S. APPLICATIONS		STATUS (Check one)		
U.S. APPLICATION NUMBER	U.S. FILING DATE	PATENTED	PENDING	ABANDONED

PCT APPLICATIONS DESIGNATING THE U.S.

PCT APPLICATION NO.	PCT FILING DATE	U.S. SERIAL NUMBERS ASSIGNED (if any)			
PCT/EP95/01357	12 April 1995				

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith. *(List name and registration number)* Peter F. Felfe, Reg. No. 20,297; John E. Lynch, Reg. No. 20,940; Alfred H. Hemingway, Jr., Reg. No. 26,736; Vincent M. Fazzari, Reg. No. 26,879; Norman D. Hanson, Reg. No. 30,946; F. Brice Faller, Reg. No. 29,532; Andrew L. Tiajoloff, Reg. No. 31,575; John A. Bauer, Reg. No. 32,554 and Vinet Kohli, Reg. No. 37,003

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201	FULL NAME OF INVENTOR: FAMILY NAME	Reinmüller	FIRST GIVEN NAME: Johannes	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP: CITY	Wiesbaden DEX	STATE OR FOREIGN COUNTRY: Fed. Rep. of Germany	COUNTRY OF CITIZENSHIP: Fed. Rep. of Germany
	POST OFFICE ADDRESS: POST OFFICE ADDRESS	Gustav-Freytag-Str. 27	CITY: D-65189 Wiesbaden	STATE & ZIP CODE/COUNTRY: Fed. Rep. of Germany
202	FULL NAME OF INVENTOR: FAMILY NAME		FIRST GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP: CITY		STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS: POST OFFICE ADDRESS		CITY	STATE & ZIP CODE/COUNTRY
203	FULL NAME OF INVENTOR: FAMILY NAME		FIRST GIVEN NAME	SECOND GIVEN NAME
	RESIDENCE & CITIZENSHIP: CITY		STATE OR FOREIGN COUNTRY	COUNTRY OF CITIZENSHIP
	POST OFFICE ADDRESS: POST OFFICE ADDRESS		CITY	STATE & ZIP CODE/COUNTRY

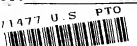
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

SIGNATURE OF INVENTOR 201	SIGNATURE OF INVENTOR 202	SIGNATURE OF INVENTOR 203
Johannes Reinmüller		
DATE 12.11.96	DATE	DATE

Anlage A

Applicant or Patentee: Johannes Reinmüller
Serial or Patent No.: 08/732,408
Filed or Issued:
For: Medical implants made of mouldings

Attorney's Docket No. HUBR 1099
PFF/MAS



VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) and 1.27(b)) - INDEPENDENT INVENTOR

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled Medical Implants made of Mouldings described in

[ ] the specification filed herewith
[X] application serial no. 08/732,408, filed October 22, 1996
[ ] patent no. _____, issued _____

I have not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

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FULL NAME _____
ADDRESS _____
[ ] INDIVIDUAL [ ] SMALL BUSINESS CONCERN [ ] NONPROFIT ORGANIZATION

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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

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